## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/526,697

Confirmation No. 9619

Applicant: Dudley et al.

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Examiner: Michail A. Belyavskyi

Docket No.: 233876 (Client Reference No. E-275-2002/1-US-02)

Customer No.: 45733

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

## DECLARATION UNDER 37 C.F.R. § 1.131

We, Mark E. Dudley, Steven A. Rosenberg, and John R. Wunderlich do hereby declare as follows:

- 1. We are the co-inventors of the pending claims in the above-referenced patent application.
- 2. We conceived of and reduced to practice the claimed invention in the United States before July 2, 2001, as evidenced by the following:
  - a. attached to this Declaration is a true and accurate copy of a report prepared by Mark E. Dudley. The report summarizes research performed involving the administration of non-myeloablative lymphodepleting chemotherapy followed by adoptive transfer of autologous T cells to melanoma patients. The autologous T-cells had been previously isolated and selected for highly avid recognition of an antigen of the melanoma by stimulation of the T-cells in vitro with the antigen of the melanoma. In patients A, B, E, and F, this in vitro stimulation of the T-cells was followed by one cycle of rapid

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expansion using irradiated allogeneic feeder cells, OKT3 antibody, and IL-2. IL-2 was subsequently administered to the patients.

- 3. The treatment dates of Patients A-F which have been deleted from the report are prior to July 2, 2001.
- 4. Each of us hereby declares that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Mark E. Dudley, Ph.D. Steven A. Rosenberg, M.D., Ph.D.
You by Wind a High MCD
John R. Wunderlich, M.D.

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